EXHIBIT 403

HDMA DEA Suspicious Orders "Best Practices"

GPPC

February 12, 2008

Today's Agenda

- HDMA efforts to date
- Background - DEA SO requirements
- Purpose & Next Steps
- Describe potential BPs
- Key points & questions for GPPC
- Additional issues

<u>Goals</u>

- Agree upon final draft BPs for Exec. Committee review
- Resolve partial shipment issue
- Receive GPPC input on BP's content & next steps

Recent HDMA Activities

Suspicious Orders

09/07/07	Meeting with DEA on suspicious orders
12/19/07	Outside Counsel recommendation to move forward
01/03/08	Request for members' existing BPs
Week of 02/07/08	Follow-up requests for BPs and interviews
01/10/08	Pain Coalition presentation
01/11/0	Contract – Wilson Security Services
01/13/08	Pharmacy Assn Meeting (NACDS, APhA, NCPA)
Week of 01/21/08	Member interviews on current practices
01/31/08	HDMA Suspicious Orders and Diversion prevention meeting - review draft BPs
02/08/08	RAC review of revised draft
02/12/08	GPPC BP review

HDMA

Recent HDMA Activities on DEA

Non-Suspicious Orders

Late Spring & Summer '07	i.d. issues; conference calls
09/11/07	Attended DEA pharmaceutical conference
09/20/07	Attended DEA methadone "public" meeting
10/16 & 17, '07	HDMA and Member DEA planning meeting
11/20/07	Filed comments on DEA self-certification proposed rule
12/03/07	"Comments" on methadone advisory
12/17/07	Meeting with Denise Curry – methadone
12/19/07	Requested that DEA provide a list of eligible methadone 40 mg recipients
01/03/08	Posted list of eligible methadone registrants on HDMA Web site
01/28/08	Filed comments on proposed rule to change Form 222 format

HDMA

Regulatory Implementation

- CSA section 301
  - DEA may promulgate and enforce any rules, regulations or procedures relating to registration and control of manufacture or distribution of controlled substances
- 21 CFR § 1301.74(b)
  - Design and operate a **system** to disclose to the registrant suspicious orders of controlled substances
  - Inform the local DEA office "**when discovered**"
  - "Suspicious order" include orders of "unusual size," deviating substantially from a normal pattern, and orders of "unusual frequency"

Security Requirements

- "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. 1301.71(a)
- "In evaluating the overall security system of a registrant or applicant, the Administrator may consider . . . The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations" *Id.* at 1301.71(b)(14)

What Has Changed? September 27, 2006 Letter

- Reporting a S.O. not enough - distributor must also maintain effective controls against diversion
- Registrant *cannot* rely solely on customer's DEA registration and state licensure
- Apparent emphasis on "internet pharmacies"

What Has Changed? December 27, 2007 Letter

- Deviation from "normal pattern" is not only determined by order size
- "Suspicious" nature of order depends not on pattern of ordering customer, but on patterns of registrant's *customer's base* and patterns "throughout . . . the regulated industry."
- "Rigid formulas" may be insufficient

December 27, 2007 Letter (continued)

- "Registrants must conduct an independent analysis of suspicious orders prior to completing a *sale*"

- "Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, ***or should have known***, that the controlled substance were being diverted." (emphasis supplied)

Purpose of BPs

- Help to sort out confusion about DEA requirements among HDMA members
- Demonstrate distribution industry's tangible efforts
- Positive PR

Next Steps

- HDMA Exec. Committee Review - Feb. 22
- Continue Pharmacy Association/Pain Coalition discussions
  - Encourage Supply Chain Partner Best Practices
- Request meeting with DEA Acting Administrator
  - Request DEA endorsement of BPs as "Safe Harbor"
  - What if request is denied (?)
- Hill visits
- BP Release Announcement (?)
- Additional options & DEA requests (?)

HDMA

Potential Best Practices
I. Know Your Customer

- Information gathering
  - Distributor requests information about the potential customers' background, customer base, credit, etc.
- Information review
  - distributor verifies completeness and *carefully* reviews information
- Investigation
  - Additional background information from non-customer sources
- Additional Recommendations

Potential Best Practices
II. Suspicious Order Monitoring

- **System design**
  - establish groups or "families" of drugs based on class of trade &/or product
- **Develop "Thresholds"**
  - Calculate "average" orders for "families"
  - Id. orders of "unusual" size/frequency/pattern
  - Cumulative orders
- **Stop shipments**

Potential Best Practices
III. Investigation of Orders of Interest; Shipment Decisions

- **Preliminary Steps**
  - Designating an Investigator(s)
- **Initial Review**
- **Investigating the Order**
  - Perform if "initial review" doesn't resolve questions
  - Contains elements of the investigation
- **Shipment Decisions and Reporting to DEA**
- **Future Customer Orders**

Potential Best Practices

IV., V. & VI. - File SO Reports With DEA; Employees, Training & SOPs; Additional Recommendations

Filing a SO Report

- Immediate DEA Notification
- Correspondence - Where/how to send

Training and SOPs

- Training for anyone involved in controlled substances
- Written SOPs

Additional Recommendations

- Periodic audits, updates, reviews, etc.

Key Points - Jan. 31 Meeting

- Implementing the BPs will expand distributors' efforts *considerably*
- Inevitably impacts customers – may be significant
- May differ based on customer type (e.g., pharmacy vs. physician)
- Includes automated systems; written SOPs etc.
- Must be *very* careful when defining "suspicious"
- Expands staff training (e.g., sales force; pickers)
- No more end of month SO reporting
- Site inspections not included (so far) but could be considered

Question A – Partial Shipments?

If a specific drug code product order is potentially suspicious, should the distributor be able to ship part of the order for that particular product *prior* to further evaluation? (7 in favor, 3 opposed, 1 abstention, 1 absent)

- **Pro**
  - Customer likely needs the product for patients
  - Customer can easily "get around" hold-up by ordering from another distributor
  - Consistent with current practice for many distributors
- **Con**
  - DEA correspondence/interpretations do not support this practice
  - DEA may reject HDMA requests to back-off aggressive actions if we press for this interpretation
  - Could result in negative PR

Question B – Timing of DEA Reports

Should the distributor report a drug code product order to DEA that triggers a threshold after the "initial review" and *before* a comprehensive "investigation"? (The alternative is to report *after* the investigation if it reveals an order is likely "suspicious"?)

- **Pro (reporting *before* investigation)**
  - "Safer" given DEA's expectations
  - Reporting decision process is clearer
  - May appear more appealing for PR purposes
- **Con (reporting *before* investigation)**
  - Unnecessary reporting may occur; DEA also wants 'true' reports
  - Customer may be subject to unwarranted DEA scrutiny if investigation later finds no problems
  - Liability unclear

Additional Issues Under Consideration

- Should Pharmacies develop BPs of their own?
- Should HDMA support an "accreditation" program – e.g., customer inspection by a 3rd party?
  - *HDMA should first talk to Pharmacy groups*
- Should HDMA recommend making the BPs a regulation?
  - Has many pros and cons
  - Some elements may not be appropriate for a regulation, but didn't rule out
  - *HDMA should prepare a final version, first; members wish to discuss internally in their companies*

THANK YOU!